

Form PTO-1449 (modified)

Atty. Docket No.

Serial No.

CLFR:114US

08/844,731

Listed Patents and Publications for Applicant's

Applicant

Staley A. Brod

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Filing Date:

April 21, 1997

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U.S. Patent Documents

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U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
SS	A1	4,409,243	10/11/83	Lieb	424	330	11/9/81
	A2	4,462,985	7/31/84	Cummins	424	85	9/7/82
	A3	5,093,338	3/3/92	Byrne	514	291	4/23/91
	A4	5,624,895	4/29/97	Sobel	514	8	2/18/94

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
SS	B1	WO 83/03411	10/13/83	WIPO			English
SS	B2	WO 96/28183	9/19/96	WIPO			English

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
SS	C1	"Interferon beta-1b is effective in relapsing-remitting multiple sclerosis. I. Clinical results of a multicenter, randomized, double-blind, placebo-controlled trial. The IFNB Multiple Sclerosis Study Group," <i>Neurology</i> 43:655-661, 1993.
	C2	Bayley <i>et al.</i> , "The transmucosal absorption of recombinant human interferon-alpha B/D hybrid in the rat and rabbit," <i>J. Pharm. Pharmacol.</i> 47(9):721-724, 1995.
	C3	Bocci <i>et al.</i> , "Is interferon effective after oral administration? The state of the art," <i>J. Biol. Regul. Homeos. Agents</i> , 4(2):81-83, 1990.
	C4	Bocci, "Absorption of cytokines via oropharyngeal-associated lymphoid tissues," <i>Clin Pharmacokinet</i> , 21(6):411-417, 1991.
	C5	Bocci, "Immunomodulators as local hormones: new insights regarding their clinical utilization," <i>Journal of Biological Response Modifiers</i> , 4:340-352, 1985.
	C6	Bosio <i>et al.</i> , "Efficacy of low-dose oral use of type I interferon in cytomegalovirus infections in vivo," <i>J. Interferon Cytokine Res.</i> , 19:869-876, 1999.

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35	C7	Brod and Khan "Oral administration of IFN- α is superior to subcutaneous administration of IFN- α in the suppression of chronic relapsing experimental autoimmune encephalomyelitis," <i>J. Autoimmunity</i> , 9:11-20, 1996.
	C8	Brod <i>et al.</i> , "Ingested (oral) IFN-alpha induces MxA mRNA in RRMS" (Submitted for publication)
	C9	Brod <i>et al.</i> , "Ingested IFN- α has biological effects in humans with relapsing-remitting multiple sclerosis," <i>Mult. Scler.</i> , 3:1-7, 1997.
	C10	Brod <i>et al.</i> , "Ingested interferon α suppresses type I diabetes in non-obese diabetic mice," <i>Diabetologia</i> , 41:1227-1232, 1998.
	C11	Brod <i>et al.</i> , "Ingested interferon alpha induces Mx mRNA," <i>Cytokine</i> , 11:1-8, 1999.
	C12	Brod <i>et al.</i> , "Ingested interferon alpha preserves residual beta cell function type 1 diabetes," <i>J. Interferon Cytokine Res.</i> , 2(12):1021-1030, 2001.
	C13	Brod, "Hypothesis: multiple sclerosis is a type I interferon deficiency syndrome," <i>Proc. Soc. Exp. Biol. Med.</i> 218:278-283, 1998.
	C14	Butcher, "The regulation of lymphocyte traffic," <i>Current Topics in Microbiology and Immunology</i> , 128:85-122, 1986.
	C15	Cantell and Pyhala, "Circulating interferon in rabbits after administration of human interferon by different routes," <i>Virology</i> , 20:97-104, 1973.
	C16	Carter <i>et al.</i> , "Disease modifying therapies in multiple sclerosis," <i>CNS Drugs</i> , 3:99-114, 1995.
	C17	Connelly, "Interferon beta for multiple sclerosis," <i>Ann. Pharmacother.</i> , 28(5):610-616, 1994.
	C18	Dhingra <i>et al.</i> , "A phase-I clinical study of low-dose oral interferon-alpha," <i>J. Immunotherapy</i> , 14(1):51-55, 1993.
	C19	Fleischmann <i>et al.</i> , "Orally administered interferons exert their white blood cell suppressive effects via a novel mechanism," <i>Neurology</i> , 13, 1993.
✓	C20	Gibson <i>et al.</i> , "Pharmacokinetics of recombinant leukocyte A interferon following various routes and modes of administration to the dog," <i>Journal of Interferon Research</i> , 5:403-408, 1985.

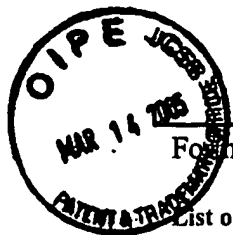
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JS	C21	Goldstein <i>et al.</i> , "Human biologic response modification by interferon in the absence of measurable serum concentrations: a comparative trial of subcutaneous and intravenous interferon- β serine," <i>Journal of the National Cancer Institute</i> , 81(14):1061-1068, 1989.
	C22	Goodkin <i>et al.</i> , "Experimental therapies for multiple sclerosis: current status," <i>Cleve. Clin. J. Med.</i> , 59:63-74, 1992.
	C23	Higgins <i>et al.</i> , "Suppression of experimental autoimmune encephalomyelitis by oral administration of myelin basic protein and its fragments," <i>J. Immunol.</i> 140:440-445, 1988.
	C24	Horisberger, "MX protein: function and mechanism of action, Biotechnology, Ciba-Geigy Ltd., CH-4002 Basel, Switzerland.
	C25	Hutchison <i>et al.</i> , "Chronic recurrent aphthous stomatitis: oral treatment with low-dose interferon alpha," <i>Mol. Biother.</i> , 2:160-164, 1990.
	C26	Koech <i>et al.</i> , "Efficacy of Kemron (low dose oral natural human interferon alpha) in the management of HIV-1 infection and acquired immune deficiency syndrome (AIDS)," <i>East Afr. Med. J.</i> , 67(7 Supp 2):SS64-70, 1990.
	C27	Koech <i>et al.</i> , "Low dose oral alpha-interferon therapy for patients seropositive for human immunodeficiency virus type-1 (HIV-1)," <i>Mol. Biother.</i> , 2(2):91-95, 1990.
	C28	Konrad <i>et al.</i> , <i>Biological Barriers to Protein Delivery</i> , ch. 14, 409-437, ed. Audus <i>et al.</i> 1993.
	C29	Larocca <i>et al.</i> , "Evaluation of neutralizing antibodies in patients treated with recombinant interferon- β ser," <i>Journal of Interferon Research</i> , 9(Supp 1):S51-S60, 1989.
	C30	Lecce <i>et al.</i> , "Treatment of rotavirus infection in neonate and weanling pigs using natural human interferon alpha," <i>Mol. Biother.</i> 2(4):211-216, 1990.
	C31	Liu <i>et al.</i> , "Accumulation of protein O-GlcNAc modification inhibits proteasomes in the brain and coincides with neuronal apoptosis in brain areas with high O-GlcNAc metabolism," <i>J. Neurochem.</i> , 89(4):1044-1055.
	C32	Mashkovskii <i>et al.</i> , "Drugs," Moscow, Meditsina, 2:389-392, 1993.
	C33	Mowat <i>et al.</i> , "The regulation of immune responses to dietary protein antigens," <i>Immun. Today</i> , 8:93-98, 1987.

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JS	C34	Nagler <i>et al.</i> , "Immunotherapy with recombinant human interleukin-2 and recombinant interferon-alpha in lymphoma patients postautologous marrow or stem cell transplant," <i>Blood</i> , 89:3951-5959.
	C35	Owens <i>et al.</i> , "The immunology of multiple sclerosis and its animal model, experimental allergic encephalomyelitis," <i>Neurol. Clin.</i> , 13(1):51-73, 1995.
	C36	Paulesu <i>et al.</i> , "Oral administration of human recombinant interferon-a2 in rats," Elsevier Science Publishers B.V. (Biomedical Division), 46:199-202, 1988.
	C37	Radwanski <i>et al.</i> , "Pharmacokinetics of interferon α -2b in healthy volunteers," <i>J Clin Pharmacol</i> , 27:432-435, 1987.
	C38	Satoh <i>et al.</i> , "Suppression of late asthmatic response by low-dose oral administration of interferon-beta in the guinea pig model of asthma," <i>J. Interferon Cytokine Res.</i> , 19:887-894, 1999.
	C39	Schafer <i>et al.</i> , "Interferon administered orally: protection of neonatal mice from lethal virus challenge," <i>Science</i> , 176:1326-1327, 1972.
	C40	Shim <i>et al.</i> , "Administration route dependent bioavailability of interferon- α and effect of bile salts on the nasal absorption," <i>Drug Dev. Indus. Pharm.</i> , 19:1183-1199, 1993.
	C41	Thompson <i>et al.</i> , "Gastric administration of type II collagen delays the onset and severity of collagen-induced arthritis in rats," <i>Clin. Exp. Immunol.</i> , 64(3):581-586, 1985.
	C42	Vial <i>et al.</i> , "Clinical toxicity of the interferons," <i>Drug Saf.</i> , 10(2):115-150, 1994.
	C43	Wedner <i>et al.</i> , <i>Basic Clinical Immunology</i> , 7 th edition Chap 34, 1991
	C44	Wills <i>et al.</i> , "Pharmacokinetics of recombinant alpha A interferon following IV infusion and bolus, IM, and PO administration to African green monkeys," <i>Journal of Interferon Research</i> , 4(3):399-409, 1984.
	C45	Witt <i>et al.</i> , "Absence of biological effects of orally administered interferon- β ser," <i>Journal of Interferon Research</i> , 12:411-413, 1992.
	C46	Yershov <i>et al.</i> , "Interferon status in different diseases," <i>Voprosy Virusologii</i> , 35:444-448, 1990 (Russian)

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DS	C47	"Mean body weight, height, and body mass index, United States 1960-2002," Advance Data From Vital and Health Statistics, CDC, US Department of Health and Human Services: Centers for Disease Control and Prevention, Number 347, October 27, 2004.

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